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10/804,778	03/19/2004	Richard A. Gross	14690.011USA	7749
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LAURENCE P. COLTON 1201 WEST PEACHTREE STREET, NW 14TH FLOOR ATLANTA, GA 30309-3488			EXAMINER	
			ISSAC, ROY P	
			ART UNIT	PAPER NUMBER
			1623	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,778

Applicant(s)

GROSS ET AL.

Examiner

ROY P. ISSAC

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 12-30 and 33-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-8, 12, 28-30 and 55-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 12, 28-30 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 11/28/07, wherein claims 4, 9-11 and 31-32 have been cancelled and claims 1-3, 5-8, 12, 28-30 have been amended, and claims 55-57 have been newly added.

Rejections Withdrawn

In view of the cancellation of claims 4, 9-11 and 31-32, all rejections made with respect to claims 4, 9-11 and 31-32 in the previous office action are withdrawn.

Applicants' amendments to claim 1 clarifying the method steps overcomes the objection of claims 1-12 and 28-31 are directed to two statutory classes of inventions.

Amendments to claims 5-7 deleting the term "based" overcomes the rejection of claims 5-7 under section 112, second paragraph as indefinite.

Amendments to claims 1-3 deleting the use steps overcomes the rejection of claims 1-12 and 28-31 under section 112, second paragraph as well as section 101.

The following are new grounds of rejection necessitated by applicants' amendments:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the step of treatment with a "primary oxide". The original specification does not support the genus of "primary oxide" as claimed herein. Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-8, 12, 28-30 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisht et. al. (JOC 64, 1999, Of record) in view of Shanbrom et. al. (U.S. Patent No. 5,545,401; PTO-892)

Bisht et. al. discloses the synthesis of sophorolipids by fermentation of *C. bombicola* which produces lactone and open chain forms of sophorolipids. (Figure 1,

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Page 780; Page 781, Column 2, Paragraphs 3-4). Bisht et. al. further discloses the use of fermented products in the treatment of cancer, autoimmune disorders, angiogenesis etc. Bisht et. al. discloses a method in which the fermentation product was isolated by extraction from which the solvent was removed to give a powder product. The product was fermented in an aqueous medium and harvested by centrifugation. This harvested product which contains aqueous media as excipient is considered dispensable solution of sophorolipids. Bisht et. al. further discloses lipase catalyzed esterification in THF and sodium methoxide. Bisht et. al. teaches that lipase activity is known to be drastically reduced in polar aprotic solvents and water is not a good medium and discloses sodium methoxide and ethoxide as appropriate solvents.

Bisht et. al. does not expressly disclose the use of another spermicidal agent or antiviral agent with sophorolipids.

Shanbrom discloses the use of providone iodine as spermicidal antiviral agents. Shanbrom further discloses a series of excipients as well.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a mixture of sophorolipids and providone iodine another antiviral agent as a combination. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements

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as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of two compounds used for the same purpose in combination would have resulted in substantially similar or additive effects in combination.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

The following are new or modified rejections necessitated by Applicant's amendment filed 11/28/07, wherein the limitations in pending claims 1-3, 5-8, 12, 28-30 and 55-57 as amended now have been changed. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, mailed 8/28/07, have been modified and are listed below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-8, 12, 28-30 and 55-57 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-9 of copending Application No. 11/020,683. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6 and 9 of the '683 application is drawn to a method of making sophorolipids via fermentation of *C. Bombicola* based on the same sophorolipid esters claimed in the instant application. The recitation of anti-viral and anti-fungal properties are intended use of the same compounds and does further limit the compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 5-8, 12, 28-30 and 55-57 are provisionally rejected on the ground of nonstatutory double patenting over claims 4-7, 10-14, and 16-21 of copending Application No. 10/807,961. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-7, 10-14, and 16-21 of the '961 application is drawn to a method of making sophorolipids via fermentation of *C.*

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Bombicola based on the same sophorolipid esters claimed in the instant application. The recitation of anti-viral and anti-sepsis properties are intended use of the same compounds and does further limit the compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 11/28/07 have been fully considered but they are not persuasive. Applicants state that they will provide appropriate disclaimers or remarks if application is allowed. However, the double patenting rejections will be maintained until terminal disclaimers are received. (MPEP 804(I)(B)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Bisht et. al. (J. Org. Chem. 1999, 64, 780-789; Of record).

Bisht et. al. discloses the synthesis of sophorolipids by fermentation of C. bombicola which produces lactone and open chain forms of sophorolipids. (Figure 1, Page 780; Page 781, Column 2, Paragraphs 3-4). Bisht et. al. further discloses the use

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of fermented products in the treatment of cancer, autoimmune disorders, angiogenesis etc. Bisht et. al. discloses a method in which the fermentation product was isolated by extraction from which the solvent was removed to give a powder product. The product was fermented in an aqueous medium and harvested by centrifugation. This harvested product which contains aqueous media as excipient is considered dispensable solution of sophorolipids.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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